

**REMARKS**

The Examiner contends that applicant's previous amendment introduced new matter into the disclosure by elimination of the term 2-9 kg per cm<sup>2</sup> from the specification on page 6, lines 32-39 and page 9, lines 7-13. As such the Examiner requires that applicants amend the specification to reintroduce the deleted term. The Examiner requires the reintroduction of the term even though it is the undersigned's understanding that the Examiners' agreed during discussion with undersigned on July 9, 2003 that the amendment was acceptable. In accordance with the Examiner's request and solely to expedite prosecution without an admission that the prior amendment introduced new matter, Applicants have reintroduced the text into the specification. The text as originally filed and as currently amended recites:

In another further aspect, the invention relates to a cosmetic method for smoothing out cellulite, wherein regional, especially sub-regional, transdermal pressure is exerted n an area of skin to be treated with 1 to 50 kg per cm<sup>2</sup> of skin, particularly preferably 2-9 kg per cm<sup>2</sup> of skin. (page 6, lines 32-39)

The shaped article is used by moving it across the region of the body to be treated, exerting pressure values of 1 to 50 kg per square centimeter, preferably 10 to 30 kg per square centimeter, particularly preferably 2 to 9 kg per square centimeter, depending on the individual condition of the skin and subcutaneous tissue. (page 9, lines 7-13)

Claims 6, 17, 18 and 23 stand rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Werding (U.S. Patent No. 3, 878,837). In particular, the Examiner contends that Applicants' invention is obvious in view of Werding who the Examiner states "discloses a massage apparatus for applying pressure and vibration to an area of skin for treatment of cellulitis." (Office Action page 2). Werding contends that his apparatus is useful for the treatment of cellulite, and achieves this goal by "percussion with lateral crushing". The claimed method involves the application of regional transdermal pressure of of 10-30 kg/cm<sup>2</sup>. The Examiner acknowledges that Werding does not teach the application of a regional transdermal pressure of 10-30 kg/cm<sup>2</sup> for treating cellulite. Therefore, even if Werding apparatus is useful for treating cellulite, Werding apparatus and Applicants' method achieve their results by processes that are different in kind.

Furthermore, Werding does not teach the level of pressure that his disclosed apparatus applies to any area of a subject. Werding states that an aim of the apparatus is to treat

cellulitis by “percussion followed by a progressive lateral crushing” (Werdning col. 1, lines 19-22) but Werdning does not disclose the results achieved by his apparatus. One of skill in the art could only speculate as to the pressures that are applied by Werdning’s apparatus and could only speculate as to the results produced by the percussion in combination with lateral crushing produced by Werdning’s apparatus and how those results compare to the results obtained by Applicant’s claimed method applying transdermal regional pressure.

The Examiner has alleged that Applicants’ application of a regional transdermal pressure of 10-30 kg/cm<sup>2</sup> for treating cellulite is obvious in view of Werdning. Applicants disagree.

Werdning refers to known massaging apparatuses which use a “progressive lateral crushing” and states:

To burst these nodules, the best results obtained to date have been by manual massage by kneading, which treatment is not without pain to the person being massaged, or by massage with a jet of water or air at pressure at about 6 atmospheres. (col. 1, lines 14-19)

The Examiner contends that the pressure of “about 6 atmospheres” as recited in Werdning is merely the pressure that achieves the “best results for bursting nodules” and therefore the Examiner concludes that 6 atmospheres is not limiting. Yet Werdning, and the Examiner, have only referred generally to other methods that use “about 6 atmospheres” in the context of a progressive lateral crushing. Werdning and the Examiner have failed to cite the references referred to in Werdning. Therefore, Applicants, as well as any other person of skill in the art are unable to evaluate the methods purportedly taught by those other non-disclosed “references”. Thus one can not evaluate what those references might teach or what they might teach against. Without access to the references alluded to by Werdning, on which the Examiner relies, one of skill in the art could only speculate and can not reasonably expect that those references teach Applicant’s method of applying a regional transdermal pressure of 10-30 kg/cm<sup>2</sup>. Furthermore, without being able to review and evaluate the methods generally referred to by Werdning one of skill in the art could not evaluate the results produced by those methods and thus cannot expect that Applicants’ method would achieve its surprising result, i.e., a

“uniform smoothing out of cellulite or effect a two dimensional, randomized and limited change of subcutaneous tissue, thus avoiding the formation of oil cysts and the associated negative concomitant phenomena, such as visible swelling” (page 8, lines 3-8).

Because the Examiner and Werding have failed to identify any particular references that describe the methods purported to use pressure of “about 6 atmospheres” (Werding col. 1, lines 14-19), it leaves Applicants without a basis to respond. Applicants respectfully request, under 37 CFR § 1.104(d)(2), that the Examiner provide the references disclosing the application of regional transdermal pressure of about or greater than 6 atmospheres or provide an Examiner's affidavit asserting that the application of regional transdermal pressure of about or greater than 6 atmosphere is common knowledge. Without such a reference or Examiner's affidavit, the rejection of the claims is improper and its' withdrawal is requested

Applicants disclosed two non-overlapping ranges of pressure 10-30 kg/cm<sup>2</sup> and 2-9 kg/cm<sup>2</sup>. The Examiner acknowledges that Applicant's range of 10-30 kg/cm<sup>2</sup> is not disclosed by the prior art. Nevertheless the Examiner contends that because Applicants cited 2-9 Kg/cm<sup>2</sup> as a particularly preferred range, Applicants are under an obligation to demonstrate that the non-overlapping range of 10-30 kg/cm<sup>2</sup> achieves some unexpected results relative to the prior art range. The Examiner contends that Applicants have not demonstrated that the range of 10-30 kg per cm<sup>2</sup> is critical to produce new and unexpected results which are different in kind and not merely in degree from the results of the prior art. Werding discloses that his apparatus acts by percussion followed by a progressive lateral crushing. Applicants method applies a regional transdermal pressure. Thus even if Werding's apparatus was useful for the treatment of cellulite, he achieves his goals by percussion with lateral crushing and not by regional transdermal pressure. Therefore even if Werding and Applicants are both treating cellulite, they are using methods that are different in kind.

In view of the foregoing remarks, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims.

Claim 24 stands rejected under 35 U.S.C. §103 for purportedly being unpatentable over Werding in view of American Health (cited in the previous Office Action). The Examiner contends Werding discloses the inventive method as claimed except for repeating the method at least once. The Examiner contends that it is “notoriously” old and well known in the massage art to repeat the procedure in order to get the results desired. As discussed

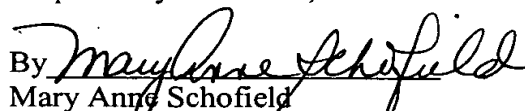
above, Werding has failed to teach or suggest the method as claimed and thus Werding and American Health, alone or in combination, fail to teach or suggest repeating the claimed method. In view of the foregoing remarks Applicants request that the Examiner reconsider and withdraw the rejection of the claim.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. WO-HUBR 1162 from which the undersigned is authorized to draw.

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Respectfully submitted,

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